## **EXHIBIT 4**

## IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
W.R. Grace & Co., et al.,	)	Case No. 01-1139 (JKF) Jointly Administered
Debtors.	) )	Jointly Administered

## AFFIDAVIT OF DR. CRAIG A. MOLGAARD

STATE OF MONTANA)
:ss
County of Missoula )

DR. CRAIG A. MOLGAARD, being first duly sworn upon oath, deposes and states as follows:

- 1. I am Dr. Craig A. Molgaard, Professor and Chair of the School of Public and Community Health Sciences, College of Health Professions and Biomedical Sciences, Skaggs Building, 353, Missoula, MT 59812. I have been a professor of epidemiology in various positions since 1983. My CV is attached to the Sur-Rebuttal Report of Dr. Craig Molgaard (epidemiology) May 2009.
- 2. The generally accepted terminology for epidemiology is set forth in Last, J.M. Ed., A Dictionary of Epidemiology (2001). Accurate use of scientific terminology is very important in epidemiology, as in all fields of science and medicine. A Dictionary of Epidemiology is a handbook sponsored by the International Epidemiology Association and published by Oxford University Press. One hundred and thirty epidemiologists world-wide contributed to the

construction of the fourth edition. According to Charles du V. Florey, President of the International Epidemiology Association, if one could only have a single volume in one's epidemiology library, it would be this one. "The dictionary's authority stems from its international recognition".

- 3. Epidemiology is divided into "observational" epidemiology and "experimental" epidemiology. Medical studies are generally "observational," because often experimental studies cannot be done on human beings. For example, it would be unethical to experiment with human beings by giving groups of people a controlled dose of asbestos, then observing the development of disease.
- 4. Observational epidemiology is divided into "analytic" epidemiology and "descriptive" epidemiology.
- 5. "Analytic" epidemiology is defined as "a study designed to examine associations, commonly putative or hypothesized causal relationships." Last, p. 5.
- 6. "Descriptive" epidemiology is defined as "a study concerned with and designed only to describe the existing distribution of variables, without regard to causal or other hypotheses." Last, p.50. Sometimes studies contain elements of both descriptive and analytic epidemiology, especially when statistical inference is introduced into the analysis. An example would be

comparison of morbidity and/or mortality in two or more populations executed by comparison of 95% confidence intervals, a form of statistical inference (testing).

- 7. Both descriptive and analytic epidemiology studies may establish an "association." An "association" is defined as "statistical dependence between two or more events, characteristics, or other variables." Last, p.7. Associations may take the form of statistical inferences such as ratios or percentages, and may or may not have statistical statements of relative certainty attached, such as p-values or confidence intervals. Each statistical association must be based upon sufficient data to have validity.
- 8. The typical descriptive study in the medical literature follows a group of patients over time, analyses clinical or mortality data, and makes clinical observations as to a disease process over time. Statistical inferences and associations are developed. This kind of study may have a companion group of normals for reference, but does not have controls per se. Most medical studies are done on volunteers or patient groups, and are not randomly selected. A descriptive study does not test a hypothesis as may be the case with an analytic study. The descriptive study develops associations, which are epidemiologic evidence. Many statements in text books of medicine are based upon associations developed in descriptive epidemiology studies, such as a case series. For example, the American Heart Association lists the case series as one design capable of establishing evidence of causation (note first Molgaard

deposition). It should also be noted that Whitehouse (2004) and the Card Mortality Study are examples of case series.

- 9. The Surveillance, Epidemiology and End Results (SEER) program of the National Cancer Institute is an example of a surveillance system that is largely descriptive epidemiology. SEER collects cancer incidence and survival data from population-based registries covering about 26% of the U.S. population. Data is collected on patient demographics, primary tumor site, tumor morphology, stage at diagnosis, first course of treatment, and follow-up for vital status (SEER Website). "Surveillance of cancer patterns is the foundation of the SEER network. It has been the primary means of measuring the national burden of cancer through incidence, morbidity, mortality and survival statistics, as well as evaluation of the impact of cancer related risk factors. Surveillance includes descriptive studies, geospatial and GIS clusters/outbreaks data, sentinel/signal early warnings, health disparities, models and methods and policy data." (SEER Web Site).
- 10. Whitehouse (2004), Whitehouse et al (2008) and the CARD Mortality Study are examples of descriptive epidemiology studies.
- 11. Analytic studies may be dose/response, testing the association between an agent and disease development. In this way a hypothesis is tested mathematically. An analytic study may be retrospective (case-control), cross-sectional or prospective (cohort). It usually has controls, which allows estimation

of odds ratios or relative risks, the basic measures of association for such designs. Such measures are point estimates, and are evaluated in terms of surrounding 95% confidence intervals. An analytic study can establish stronger associations, and stronger statistical statements, and may contribute to evidence of causality, but in and of itself does not constitute causality, but association.

12. In epidemiology, causality requires strong evidence before a particular event or agent is considered to have caused a particular phenomena. Generally in epidemiology, all propositions remain hypotheses until proven by replication. In epidemiology proof requires formal testing and replication. Even then strong associations are necessary for causation. A conclusion on causation or a prediction based on analytic epidemiology may require exhaustive and replicated work from various medical and scientific fields. An example is the theoretical orientation known as ecoepidemiology. According to Last (p. 56), following Susser (1998), this is "a conceptual approach that unifies molecular, social, and population- based epidemiology, in a multilevel application of methods aimed at identifying causes, categorizing risks, and controlling public health problems." Its focus is on ecological influences on human health, whether toxins or parasites. It is quite different than a single ecological study, as it involves multiple studies reaching down to the molecular level of joint distribution of exposure and disease for individuals in a given population.

As an example, in the asbestos insulators' studies observations on death

rates though documented by data remain as hypotheses. Not all individuals in the insulators cohort have died as yet. The observed rates could change if updated in a new study. The death rates remain as unproven hypotheses, because the studies have not been replicated. Both the CARD Mortality Study and the Markowitz et al (1998) insulators study have over 70 deceased subjects, and accordingly the associations and statistical inferences drawn are quite strong.

- 13. Associations developed through descriptive epidemiology and/or analytic epidemiology may be used as generalizations and often form the basis for public health decisions. Using the Libby asbestos site as an example, since clinical trials of asbestos dosing would be unethical, descriptive studies become more important. The EPA's "Determination and Findings of Public Health Emergency for the Libby Asbestos Site in Lincoln County, Montana" of 6/17/09 relies in part on a collection of descriptive studies including Whitehouse (2004), Peipins et al (2003), and Horton et al (2006), and serves as an example of ecoepidemiology conceptualizations of causality.
- 14. A classic example of descriptive epidemiology being used to determine health policy is a descriptive study carried out at the Mayo Clinic, examining rates of Guillaume Barre Syndrome. Kurland and Molgaard, "the Patient Record in Epidemiology," Scientific American 1981 (245) 54-63.

DATED this 31 day of August, 2009.

Craig A. Molgaard, M.D.

SUBSCRIBED AND SWORN to before me this 31 day of August, 2009.

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Notary Public for the State of Montana

Residing at: Missoula, Montana
My Commission Expires: June 15.208